#22

copy of the supporting statement for this information collection is available on the Internet at "http://www.fda.gov/ohrms/dockets".

Dated: February 23, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99-5030 Filed 3-1-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E-0839]

Determination of Regulatory Review Period for Purposes of Patent Extension; Atacand

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Atacand and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Atacand (candesartan cilexetil). Atacand is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Atacand (U.S. Patent No. 5,196,444) from Takeda Chemical Industries Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 16, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Atacand represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Atacand is 1,087 days. Of this time, 686 days occurred during the testing phase of the regulatory review period, while 401 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* June 15, 1995. The applicant claims May 16, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 15, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* April 30, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for Atacand (NDA 20,838) was initially submitted on April 30, 1997.

3. *The date the application was approved:* June 4, 1998. FDA has verified the applicant's claim that NDA 20,838 was approved on June 4, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 413 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 3, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before August 30, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the ¶docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 16, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99-5032 Filed 3-1-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-228]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the

DSD

McKinney
&Stringer
a professional corporation

August 3, 1999

DIRECT NUMBER: 405/272-1915
E-MAIL: OCONNELLS@MCKINNEYSTRINGER.COM
REPLY TO OKLAHOMA CITY OFFICE

PATENT
Att'y Dkt. No. 84660-0045

Commissioner for Patents and Trademarks
Washington, D.C. 20231

07224550

Re: Applicant: Patrick H. Flores
Patent No.: Des. 318,039
Issue Date: July 9, 1991
For: VEHICLE RUNNING BOARD

Transmitted herewith is a Change of Attorney's Address In Patent in the above-referenced patent, and a pre-addressed postal card.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 13-2493.

SEAN V. O'CONNELL, Reg. No. 42,951
McKINNEY & STRINGER, P.C.
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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited on August 3, 1999, with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Sean V. O'Connell
Name of Applicant, assignee or registered representative

Signature

August 3, 1999
Date

DSD

McKinney
&Stringer
a professional corporation

August 3, 1999

DIRECT NUMBER: 405/272-1915
E-MAIL: OCONNELLS@MCKINNEYSTRINGER.COM
REPLY TO OKLAHOMA CITY OFFICE

PATENT
Att'y Dkt. No. 84661-0011

Commissioner for Patents and Trademarks
Washington, D.C. 20231 07094535

Re: Applicants: Andrew G. Butler and Ronald Wisnia
Patent No.: Des. 308,644
Issue Date: June 19, 1990
For: CARPENTER LEVEL

Transmitted herewith is a Change of Attorney's Address In Patent in the above-referenced patent, and a pre-addressed postal card.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 13-2493.

SEAN V. O'CONNELL, Reg. No. 42,951
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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

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Sean V. O'Connell
Name of Applicant, assignee or registered representative

Signature

August 3, 1999
Date

☐ DESIGN ☒ UTILITY PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Patrick H. Flores		
Patent No.:	Des. 318,039	Examiner:	James M. Gandy
Issue Date:	July 9, 1991	Att'y Dkt.:	084660-0045
For:	VEHICLE RUNNING BOARD		

Commissioner for Patents and Trademarks
Washington, D.C. 20231

CHANGE OF ATTORNEY'S ADDRESS IN PATENT

Effective immediately, please send all correspondence for this patent as follows:

Sean V. O'Connell, Reg. No. 42,951
McKINNEY & STRINGER, P.C.
Corporate Tower
101 North Robinson, Suite 1300
Oklahoma City, Oklahoma 73102-5504

Please direct telephone calls to:

Phone: (405) 272-1915
Fax: (405) 239-7902

Respectfully submitted,

SEAN V. O'CONNELL, Reg. No. 42,951
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Oklahoma City, Oklahoma 73102-5504
Phone: 405/272-1915
Fax: 405/239/7902
Attorney for Applicant

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited on August 3, 1999, with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Sean V. O'Connell		August 3, 1999
Name of Applicant, assignee or registered representative	Signature	Date

SVO/tds/358261

12-09-99

DSD

UNITED STATES PATENT AND TRADEMARK OFFICE

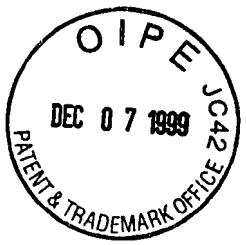
Appl. no. 07/543,153

Filed: 19900625

Patent no.: D320,454

Issued: 19911001

Customer number: 21121



REQUEST TO CORRECT ATTORNEY DOCKET NUMBER IN PALM SYSTEM

The attorney docket number in the Palm system for the above-referenced file is incorrect. It is supposed to be:

PROPD002US

It is respectfully requested that this attorney docket number be corrected in the Palm system.

Carl Oppedahl

Carl Oppedahl
PTO Reg. No. 32,746
Oppedahl & Larson LLP
P O Box 5270
Frisco, CO 80443-5270
email: oppedahl@patents.com

12-09-99

DSP

UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. no. 07/371,663

Filed:

Patent no.: Re 33,528

Issued:

Customer number: 21121

REQUEST TO CORRECT ATTORNEY DOCKET NUMBER IN PALM SYSTEM

The attorney docket number in the Palm system for the above-referenced file is incorrect. It is supposed to be:

~~US~~ DOTY P003US

It is respectfully requested that this attorney docket number be corrected in the Palm system.

Carl Oppedahl

Carl Oppedahl
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DSD

Please type a plus sign (+) inside this → [+] **71052-7**

PTO/SB/123 (8-96)
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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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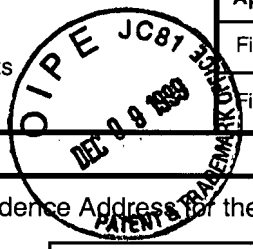
CHANGE OF CORRESPONDENCE ADDRESS
Patent

Address to:
Assistant Commissioner for Patents
Washington, D.C. 20231



Patent Number	**5,779,859**
Issue Date	**July 14, 1998**
Application Number	**08/766260**
Filing Date	**December 13, 1996**
First Named Inventor	**Carter**

Please change the Correspondence Address for the above-identified patent to:

[x] Customer Number **022902** → *Type Customer Number here*

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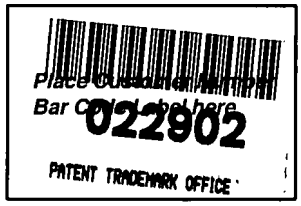

Firm *or* Individual Name	**Christopher W. Brody**				
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Country	**USA**				
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I am the :

[ ] Patentee.

[ ] Assignee of record of the entire interest.
Certificate under 37 CFR 3.73(b) is enclosed.

[x] Attorney or agent of record .

Typed or Printed Name	**Christopher W. Brody**	**Reg. No. 33,613**
Signature	Christopher W. Brody	
Date	**December 10, 1999**	

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